OCT 21 2011

SECTION 5 – 510(K) SUMMARY

K112166 P1 of 3

Applicant:

W and R Investments, LLC d/b/a
Laser Engineering
113 Cedar Street
Suite S5
Milford, MA 01757
Tel: (508) 520-2552

Contact Person:
Robert I. Rudko, Ph.D.
Chief Scientist
rrudko@laserengineering.com

Date Prepared: July 19, 2011

Device Name: CO_2 Laser Waveguide

Proprietary Name:	UltraLase Flexible CO_2 Laser Waveguide
Classification Name:	Laser Surgical Instrument
Classification:	878.4810
Product Code:	GEX

Predicate Devices:

The UltraLase Flexible CO_2 Laser Waveguide is substantially equivalent to the following devices:

Device	Manufacturer	510(k) No.
FiberLase CO_2 Laser Waveguide	Lumenis Ltd	K100384
SureGuide CO_2 Laser Beam Delivery System	Clinicon Corp.	K992472
Beam Path CO_2 Mark III WaveGuide Fiber	OmniGuide, Inc.	K070157

Device Description:

The UltraLase Flexible CO_2 Laser Waveguide is a laser delivery system for use in surgical procedures where a flexible delivery system would allow easier and more efficient delivery of laser energy to the targeted tissue. The waveguide consists of a flexible silica capillary whose inside wall has been coated with a durable coating that is highly reflective at the intended wavelength of use. A fiber optic connector is attached to the proximal end of the waveguide and the waveguide is covered with a plastic sleeve for protection. The UltraLase Flexible CO_2 Laser Waveguide is supplied with a single use handpiece attached or without a handpiece so it can be used with various reusable handpieces such as the TTI Medical ACCU-Beam Fiberoptic Handpieces.

The UltraLase Flexible CO_2 Laser Waveguide is designed to operate at 10.6µm and has a broad enough transmission band to accommodate any laser operating in this region.

The laser energy is coupled into the waveguide using the supplied focusing lens and travels down the waveguide by multiple bounces off the inner reflective surface, exiting to the tissue at the distal end.

The UltraLase Flexible CO_2 Laser Waveguides come with either a 905 SMA connector or a 953 ST connector and are therefore can be used with any CO_2 Laser that is compatible with one of these connectors. The waveguide is supplied in several diameters and lengths as shown in the following chart.

Core Dia. (µm)	Outer Dia. (µm)	Lengths (cm)
300	750	100, 150
500	850	100, 150, 200
750	1200	100, 150, 200

It is recommended that a purge gas system using an inert gas such as helium be used to force an inert gas through the waveguide for cooling and to keep the inner channel of the waveguide free of debris.

The waveguides delivery systems are supplied sterile for single use.

Indications for Use:

The UltraLase Flexible CO_2 Laser Waveguide is indicated for use with CO_2 laser systems for general and plastic surgery procedures neurosurgery, ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, gynecology and urology procedures. It is used to deliver laser energy for incision, excision, ablation, vaporization, and coagulation of soft tissues.

The UltraLase Flexible CO_2 Laser Waveguide can be used in open surgical procedures and endoscopic procedures.

The indications for use for which the delivery system is used are dependent upon the cleared indications for use of the laser system and laser system accessories to which it is attached.

Technological Characteristics Compared to Predicate Device:

After reviewing the technological characteristics (overall design, mechanism of action, mode of operation and performance characteristics) and the indications for use, it has been determined by Laser Engineering that the UltraLase Flexible CO_2 Laser Waveguide is substantially equivalent to existing legally marketed devices.

Performance testing:

The UltraLase Flexible CO_2 Laser Waveguides are bench tested to establish transmission bandwidth, and percent transmission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 21 2011

W and R Investments, LLC d/b/a
Laser Engineering
% Robert I. Rudko, Ph.D.
113 Cedar Street, Suite S5
Milford, Massachusetts 01757

Re: K112166
Trade/Device Name: UltraLase Flexible CO_2 Laser Waveguide
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 19, 2011
Received: July 28, 2011

Dear Dr. Rudko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number: K112166

Device Name: UltraLase Flexible CO_2 Laser Waveguide

Indications for Use:

The UltraLase Flexible CO_2 Laser Waveguide is indicated for use with CO_2 laser systems for general and plastic surgery procedures, neurosurgery, and ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, gynecology and urology procedures. It is used to deliver laser energy for incision, excision, ablation, vaporization, and coagulation of soft tissues.

The UltraLase Flexible CO_2 Laser Waveguide can be used in open surgical procedures and endoscopic procedures.

The indications for use for which the delivery system is used are dependent upon the cleared indications for use of the laser system and laser system accessories to which it is attached.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical [illegible]pedic,
and Restorative Devices

510(k) Number K112166